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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

FREDERIC BONTE et al

Serial No.: 09/508,670

Filed: March 28, 2000

Group Art Unit: 1617

Examiner: S. Sharareh

#15  
HND  
12/19/02

For: A METHOD OF COSMETIC CARE USING ELLAGIC ACID,  
ITS SALTS, METAL COMPLEXES, ETHERS AND  
ACYLATED DERIVATIVES THEREOF

#### RESPONSE

Honorable Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

The following remarks are submitted in response to  
the Office action mailed August 13, 2002.

Claims 17 through 25, 35 through 39 and 70 have been  
rejected under 35 USC 112, first paragraph, as containing  
subject matter not sufficiently described in the  
specification. The Office action specifically objects that  
the disclosure lacks sufficient written description for  
claimed methods of "improving dermis-epidermis cohesion  
comprising administering ellagic acid to a subject in need  
thereof."

Moreover, the Office action alleges that the state  
of the art concerning the cohesion between dermis and

epidermis is not well established, and there is no certainty whether cohesiveness of dermis and epidermis is a function of skin ageing or lack of collagen VII in all possible subjects encompassed by the instant claims.

Initially, Applicants note that the object of the invention is set forth at the top of page 3 of the present specification where it is stated that the compositions of the invention are useful in all applications "where it is desired to increase the proportion of collagen VII, particularly with a view on the one hand to favoring the cohesion between the dermis and the epidermis... Such compositions make it possible in particular to favor the cohesion between the dermis and the epidermis in persons whose skin is atonic or loose."

Further, on page 10 of the specification in discussing the results of Example 1, it is stated that "[a]s collagen VII is in particular the main constituent of the anchoring fibrils, it is clearly apparent from this test that ellagic acid and its derivatives according to the invention can advantageously be used as agents for reinforcing the dermal-epidermal junction and thereby improving the cohesion between the dermis and the epidermis."

Moreover, Applicants point out that it is well known in the art that an increase of collagen VII necessarily improves cohesion between dermis and epidermis. Submitted

herewith are Abstracts of the following references discussing this subject matter:

Collagen VII & Dermo-Epidermal Junction

Intracellular Accumulation of Collagen VII in Cultured Keratinocytes From a Patient.....

J Invest Dermatol Jan. 1994 102(1):105-10  
Konig et al

Transforming Growth Factor-beta Promotes Deposition of Collagen VII in a Modified Organotypic Skin Model  
Lab Invest 1994 Feb. 70(2):203-9  
Konig et al

Three-Dimensional Distribution of Basement Membrane Components in Dystrophic Recessive Epidermolysis...  
J Pathol 1996 Aug. 179(4):427-31  
Muda et al

Most Anchoring Fibrils in Human Skin Originate and Terminate in the Lamina Densa  
Lab Invest 1997 Jun. 76(6):753-63  
Shimizu et al

Dermo-Epidermal Junction and Skin Aging

Uva Irradiation Stimulates the Synthesis of Various Matrix-Metalloproteinases (MMPs) in Cultured....  
Exp Dermatol Mar. 1993 2(2):92-7  
Wlaschek et al

Treatment of Photodamage with Topical Tretinoin: An Overview  
J am Acad Dermatol 1997 Mar. 36(3) Pt 2): S27-36  
Gilchrest

Clinical Features of Photodamaged Human Skin are Associated With a Reduction in Collagen VII  
Br J. Dermatol 1997 Sept. 137(3):344-50  
Craven et al

Age-Related Functional and Structural Changes in Human Dermo-Epidermal Junction Components  
J Investig Dermatol Symp Proc 1998 Aug. 3(2):172-9  
Le Varlet et al

These documents were published before the priority date of the present application and show that the relationship between the synthesis of collagen VII and the dermal-epidermal junction was well known before the filing date of the present application. Concerning the relationship between synthesis and collagen VII and dermo-epidermal junction, Journal of Investigative Dermatology 1994 January 102(1):105-10 indicates that a deficiency in collagen VII leads to intercellular accumulation and degradation of this collagen, and thus to a reduced number of anchoring fibrils at the dermo-epidermal junction, and subsequently to blistering of the skin.

Thus, it is clear from the enclosed references that there is a relationship between collagen VII synthesis and the quality of the dermal-epidermal junction. Applicants have proposed a method for stimulating the synthesis of collagen VII, and thereby improving the quality of the dermal-epidermal junction. This relationship is disclosed clearly in the present specification, as is a method for improving collagen VII synthesis in order to improve the dermal-epidermal junction; a number of compositions are disclosed which may be applied to the skin in order to accomplish this purpose. Thus, it is not seen how it can be alleged that the specification does not provide one of ordinary skill in the art with sufficient information to practice the invention, and withdrawal of this rejection is requested.

Claims 17 through 24, 35-36 and 70 have been rejected under 35 USC 102(b) over the Arima et al patent. Applicants submit that the claimed invention is patentable over the cited reference.

Arima et al discloses compositions for external application containing ellagic acid in an amount of 0.001 to 20%, an amino acid and other suitable topical excipients. Arima et al is directed to skin lightening, and does not disclose or suggest improving collagen VII synthesis or improving the dermal-epidermal junction.

In this regard, the Office action takes the position that "[i]n process claims, a recitation of the intended use does not impart patentability if the intended use does not result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, USPQ 458, 459 (CCPA 1963)."

With regard to *In re Casey*, the claims in the application at issue were directed to an apparatus, and the court held that "[t]he manner or method in which such machine is to be utilized is not germane to the issue of patentability of the machine itself." In this regard, Applicants note that the present claims are not directed to compositions, but rather to methods of treatment, and for that reason the holding of *In re Casey* is not applicable.

In *In re Otto*, the claims were directed to an article of manufacture and a method for making the article of manufacture, and the court held that the method of use of such a device cannot impart patentability to the article and method of making the article. Accordingly, *In re Otto* is also not applicable to the present situation.

Because the claimed invention is directed to the method of use, and not to the composition itself, and because Arima et al does not disclose a method for improving collagen VII synthesis, Applicants submit that the claimed invention is not anticipated by Arima et al and withdrawal of this rejection is requested.

Claims 17 through 25, 35 through 39 and 70 have been rejected under 35 USC 103 over Arima et al in view of Solar et al, and Seguin et al. The patent to Arima et al has been discussed in detail above, and Applicants rely on that discussion.

Both Solar et al and Seguin et al have been cited to show that *Pygenum africanum* is known for use in topical cosmetic and topical pharmaceutical compositions. However, neither of these references discloses or suggests that ellagic acid might be used to improve collagen VII synthesis, and therefore the secondary references do not cure the defects of the Arima et al reference.

Withdrawal of this rejection is requested.

An early allowance of the application is earnestly solicited.

Respectfully submitted,



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